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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,766	12/29/2006	Hideki Hasegawa	43512-103808	5560
23644 7590 02/26/2010 BARNES & THORNBURG LLP P.O. BOX 2786 CHICAGO, IL 60690-2786				
EXAMINER				
BOESEN, AGNIESZKA				
ART UNIT		PAPER NUMBER		
1648				
NOTIFICATION DATE		DELIVERY MODE		
02/26/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent-ch@btlaw.com

Office Action Summary

Application No.

10/567,766

Applicant(s)

HASEGAWA ET AL.

Examiner

AGNIESZKA BOESEN

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Amendment filed November 3, 2009 in response to the Office Action of May 13, 2009 is acknowledged and has been entered. Claim 11 has been amended. Claims 1-10 and 15-18 are withdrawn. Claims 11-14 are under examination in this Office action.

Claim Rejections - 35 USC § 112

Rejection of Claims 11-14 under 35 U.S.C. 112, first paragraph, **is withdrawn** in view of Applicant's amendment.

Claim Rejections - 35 USC § 102

Rejection of Claims 11-14 under 35 U.S.C. 102(b) as being anticipated by Wang et al. (Journal of Clinical Investigation, 2002, Vol. 110, p. 1175-1184) **is withdrawn** in view of Applicant's amendment.

New Rejection in view of Applicant's amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hilleman et al. (US Patent 3,609,092) in view of Wong et al. (Antimicrobial Agents and Chemotherapy. 1995, Vol. 39, p. 2574-2576 in IDS on 5/8/2008).

Hilleman teaches methods of intramuscular administration of a composition comprising influenza vaccine containing influenza virus antigen and a double stranded RNA (Poly I:C) in aqueous physiological solution (see claims 1-15 and Examples 1-6 and Example 12). Hilleman teaches administering the composition at least twice (see page 2575).

Hilleman does not teach administering the composition to the nasal mucosa. Hilleman does not teach administering the composition at an interval of at least one week or more.

Wong teaches administering double stranded RNA (Poly I: C) to the nasal mucosa (see page 2574). Wong teaches administering two doses of the double stranded RNA (Poly I: C) (see page 2572). Wong teaches that double stranded RNA (Poly I: C), due to its ability to modulate the immune responses including interferon induction and activation of natural killer cells, provides a highly effective prophylaxis against respiratory influenza A virus infection (see page 2575 right paragraph). Wong teaches that all mice pretreated with intranasal dose of double stranded RNA (Poly I: C) were protected against the challenge with influenza virus while only 40% of mice pretreated with intraperitoneal dose survived the virus challenge (see page 2575).

It would have been *prima facie* obvious to administer Hilleman's composition comprising influenza vaccine containing influenza virus antigen and double stranded RNA (Poly I:C) to the nasal mucosa as taught by Wong. It would have been within the skill of the ordinary artisan to optimize the dosing time to administer the two doses of the composition taught in Hilleman and Wong at an interval of at least one week or more.

One would have been motivated to administer Hilleman's influenza vaccine and a double stranded RNA (Poly I:C) to the nasal mucosa because Wong teaches that all mice pretreated with intranasal dose of double stranded RNA (Poly I: C) were protected against the challenge with

influenza virus while only 40% of mice pretreated with the intraperitoneal dose survived (see page 2575) and because Wong teaches that double stranded RNA (Poly I: C) provides a highly effective prophylaxis against respiratory influenza A virus infection (see page 2575 right paragraph).

One would have had a reasonable expectation of success to administer Hilleman's composition to the nasal mucosa as taught by Wong because intranasal administration of antigens has been successfully practiced in the art as evidenced by Wong.

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground of rejections presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Agnieszka Boesen/
Examiner, Art Unit 1648

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit
1648